PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P/1757-69	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/35875	International filing date *(day/month/year)* 06 November 2003 (06.11.2003)	Priority date *(day/month/year)* 07 November 2002 (07.11.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61N 1/05 and US Cl.: 607/126		
Applicant AXIOM MEDICAL INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
04 June 2004 (04.06.2004)	25 January 2005 (25.01.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Kennedy Schaetzle Telephone No. 703 308-0858

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/35875

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed.

☒ the description:
pages 1-9 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages NONE, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages 10-17, filed with the letter of 16 December 2004 (16.12.2004)

☒ the drawings:
pages 1-7, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/35875

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	21, 22, 30-32, 36, 37	YES
	Claims	1-20, 24-29, 34, 35, 39	NO
Inventive Step (IS)	Claims	23, 33, 38	YES
	Claims	1-22, 24-32, 34-37, 39	NO
Industrial Applicability (IA)	Claims	1-39	YES
	Claims	NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-20, 24-29, 35 and 39 lack novelty under PCT Article 33(2) as being anticipated by Van Wijk et al..

Claims 21, 22, 30-32, 36 and 37 lack an inventive step under PCT Article 33(3) as being obvious over Van Wijk et al. in view of Lowe et al.. Van Wijk et al. do not disclose the use of a chest tube with a groove formed in the peripheral wall. The use of chest tubes containing this feature is, however, taught by Lowe et al. to allow for removal of tube apparatus as needed, while leaving sensor structure in the body (see elements 112 of Fig. 10). The general use of chest tubes is taught by Lowe et al. to allow for the collection of valuable diagnostic information following heart surgery. Since both Van Wijk et al. and Lowe et al. are concerned with post surgical apparatus and temporary pacing procedures, and since the particular type of post-surgical treatment and diagnostic data techniques employed have long been recognized to be a matter of physician prerogative dependent upon the condition of the patient, those of ordinary skill in the art would have seen the obviousness of employing the flexible treatment chest tube structure of Lowe et al. in the temporary pacing wire system of Van Wijk et al. Lowe et al. further go on to declare that temporary heart pacing wires (first and second pacing wires are shown in Fig. 17) may be interconnected with the tube as per col. 11, lines 1-21. Elongated structure 110 (Fig. 10) can be removed when no longer required to leave the probe receiving tube and thus the temporary pacing wires in the body (note col. 10, lines 29-38).

Claim 34 lacks an inventive step under PCT Article 33(3) as being obvious over Van Wijk et al.. The use of anesthesia for surgical procedures of the type required by the practice of the Van Wijk et al. method would necessitate the use of a tube for delivering anesthesia. To therefore incorporate such a tube would have been considered blatantly obvious to relieve patient trauma.

Claims 23, 33 and 38 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the use of the recited film enclosing the heart wire within the groove for allowing releasable removal.

Claims 1-39 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

---------- NEW CITATIONS ----------

US 6,330,481 B1 (VAN WIJK et al.) 11 December 2001, see entire document.

WHAT IS CLAIMED IS:

1. A surgical heart stimulation system comprising:

a wire having a proximal end and a distal end, at least part of the distal end being conductive so as to be usable in heart stimulation; and

a surgical pledget for being attached to said distal end of said wire, said surgical pledget being adapted for non-invasively maintaining said distal end in position adjacent the heart.

2. The surgical heart stimulation system of claim 1, wherein said distal end of said wire has a wire end structure comprising an irregular or three-dimensional, atraumatic structure adapted for engaging said surgical pledget when secured to the heart, for maintaining said heartwire in position relative to said surgical pledget and thereby relative to the heart.

3. The surgical heart stimulation system of claim 2, wherein said end structure comprises at least one of a pigtail, a hook, a tine and a suture sized and shaped for engaging said pledget so as to maintain said heartwire in said position.

4. The surgical heart stimulation system of claim 1, wherein said pledget is made of cotton or Teflon.

5. The surgical heart stimulation system of claim 1, further comprising a second wire having a corresponding proximal end and distal end; and

attached to the distal end of the second wire, a second wire end structure adapted for non-invasively maintaining said distal end in position adjacent the heart.

6. The surgical heart stimulation system of claim 5, wherein said second wire end structure comprises an irregular or three-dimensional, atraumatic

structure adapted for engaging a surgical pledget secured to the heart, for maintaining said heartwire in position relative to said surgical material.

7. The surgical heart stimulation system of claim 6, further comprising a second surgical pledget for being attached to said distal end of said second wire via said second end structure.

8. The surgical heart stimulation system of claim 5, wherein said first and second wires are comprised in a bipolar heartwire.

9. An arrangement for stimulating a heart, comprising in combination:

a surgical pledget for being secured to the heart; and

a heartwire comprising a wire having a proximal end and a distal end, at least part of the distal end being conductive so as to be usable in heart stimulation, and having an end structure comprising an irregular or three-dimensional, atraumatic structure adapted for engaging said surgical pledget when secured to the heart, for maintaining said heartwire in position relative to said surgical pledget and thereby relative to the heart;

said surgical pledget being adapted for non-invasively maintaining said distal end in position adjacent the heart.

10. The arrangement of claim 9, wherein said end structure comprises at least one of a pigtail, a hook, a tine and a suture sized and shaped for engaging said pledget so as to maintain said heartwire in said position.

11. The arrangement of claim 9, further comprising a second wire having a corresponding proximal end and distal end;

attached to the distal end of the second wire, a second end structure adapted for non-invasively maintaining said distal end in position adjacent the heart;

wherein said second end structure comprises an irregular or three-dimensional, atraumatic structure adapted for engaging a surgical pledget secured to the heart, for maintaining said heartwire in position relative to said surgical material.

12. The arrangement of claim 11, further comprising a second surgical pledget for being secured to the heart for engaging the distal end of the second wire.

13. A method of maintaining a heartwire in position relative to a heart for cardiac pacing, comprising the steps of:

securing a surgical pledget to the heart;

providing an irregular or three-dimensional, atraumatic end structure on a pacing end of said heartwire; and

placing said end structure adjacent said surgical pledget, said end structure being adapted for engaging said surgical pledget so as to maintain said heartwire in said position relative to said surgical pledget and thereby relative to said heart.

14. The method of claim 13, further comprising the steps of forming said end structure as at least one of a pigtail, a hook, a tine and a suture sized and shaped for engaging said pledget so as to maintain said heartwire in said position; and placing said end structure under said pledget.

15. A method of maintaining a pair of heartwires in position relative to a heart for cardiac pacing, comprising the steps of:

securing a pair of surgical pledgets to the heart;

providing irregular or three-dimensional, atraumatic end structures on respective pacing ends of said heartwires; and

placing said end structures adjacent respective ones of said surgical pledgets, said end structures being adapted for engaging said surgical pledgets so

as to maintain said heartwires in said position relative to said surgical pledgets and thereby relative to said heart.

16. The method of claim 15, further comprising the steps of forming each of said end structures as at least one of a pigtail, a hook, a tine and a suture sized and shaped for engaging said pledgets so as to maintain said heartwires in said position; and placing said end structures under said pledgets.

17. The method of claim 15, wherein said pair of heartwires are comprised in a bipolar heartwire.

18. A surgical heart stimulation system, comprising in combination a chest tube and a heartwire secured thereto;

said heartwire comprising a wire having a proximal end and a distal end, at least part of the distal end being conductive so as to be usable in heart stimulation; and further comprising a surgical pledget for being attached to said distal end of said wire, said surgical pledget being adapted for non-invasively maintaining said distal end in position adjacent the heart;

attached to said distal end of said heartwire, an end structure comprising an irregular or three-dimensional, atraumatic structure adapted for engaging said surgical pledget when secured to the heart, for maintaining said heartwire in position relative to said surgical pledget and to said heart.

19. The combination of claim 18, wherein said end structure comprises at least one of a pigtail, a hook, a tine and a suture sized and shaped for engaging said pledget so as to maintain said heartwire in said position.

20. The combination of claim 18, wherein said heartwire is secured to said chest tube by an elongated structure attached to said chest tube.

21. The combination of claim 20, wherein said elongated structure is a groove formed in a peripheral wall of said chest tube.

22. The combination of claim 21, wherein said heartwire is removable from said groove while still maintaining said heartwire in position relative to said surgical pledget and to said heart.

23 . The combination of claim 22, wherein said groove is covered by a film which encloses said heartwire in said groove and is releasable for removing said heartwire from said groove.

24. The combination of claim 20, wherein said elongated structure is attached to a peripheral wall of said chest tube.

25. The combination of claim 24, wherein said elongated structure is removable from said chest tube while still maintaining said heartwire in position relative to said surgical pledget and to said heart.

26. The combination of claim 20, wherein said heartwire is removable from said elongated structure while still maintaining said heartwire in position relative to said surgical pledget and to said heart.

27. The combination of claim 18, wherein said heartwire further comprises a second wire having a proximal end and a distal end, at least part of the distal end being conductive so as to be usable in heart stimulation, and

further comprising a second surgical pledget for being attached to said distal end of said second wire, said second surgical pledget being adapted for non-invasively maintaining said distal end of said second wire in position adjacent the heart;

attached to said distal end of said second wire, an end structure comprising an irregular or three-dimensional, atraumatic structure adapted for engaging said second surgical pledget when secured to the heart, for maintaining said heartwire in position relative to said second surgical pledget and to said heart.

28. The combination of claim 27, wherein said first and second wires are comprised in a bipolar heartwire.

29. A surgical method comprising the steps of:

securing a surgical pledget to a patient's heart;

placing a chest tube and a heartwire secured thereto in the patient's chest cavity;

said heartwire comprising a wire having a proximal end and a distal end, at least part of the distal end being conductive so as to be usable in heart stimulation; and attached to said distal end, an end structure comprising an irregular or three-dimensional, atraumatic structure; and

engaging said end structure with said surgical pledget secured to the heart, for maintaining said heartwire in position relative to said surgical pledget and to said heart.

30. The method of claim 29, wherein said heartwire is secured by an elongated structure to said chest tube, and further comprising the step of removing said elongated structure from said chest tube while still maintaining said heartwire in position relative to said surgical pledget and to said heart.

31. The method of claim 29, further comprising the step of removing said heartwire from said chest tube while still maintaining said heartwire in position relative to said surgical pledget and to said heart.

32. The method of claim 29, wherein said heartwire is disposed in a groove formed in a peripheral wall of said chest tube, and further comprising the step of removing said heartwire from said groove while still maintaining said heartwire in position relative to said surgical pledget and said heart.

33. The method of claim 32, wherein said groove is covered by a film which encloses said heartwire in said groove and is releasable for removing said heartwire from said groove.

34. The combination of claim 18, further comprising at least one anesthesia delivery tube attached to said chest tube for delivering post-operative local anesthesia to the chest cavity of the patient.

35. The combination of claim 18, further comprising at least one wire attached to said chest tube and usable for carrying cardiac output monitoring signals.

36. In combination, a chest tube and a heartwire secured thereto;

said heartwire comprising a wire having a proximal end and a distal end, at least part of the distal end being conductive so as to be usable in heart stimulation; and

attached to said distal end, an end structure comprising an irregular or three-dimensional, atraumatic structure adapted for engaging a surgical material secured to the heart, for maintaining said heartwire in position relative to said surgical material and to said heart;

wherein said heartwire is disposed in a groove formed in a peripheral wall of said chest tube.

37. The combination of claim 36, wherein said heartwire is removable from said groove while still maintaining said heartwire in position relative to said surgical material and to said heart.

38. The combination of claim 37, wherein said groove is covered by a film which encloses said heartwire in said groove and is releasable for removing said heartwire from said groove.

39. In combination, a chest tube and a heartwire secured thereto;

said heartwire comprising a wire having a proximal end and a distal end, at least part of the distal end being conductive so as to be usable in heart stimulation; and

said chest tube having a proximal end and a distal end;

said proximal end of said heartwire being secured to the proximal end of said chest tube;

said distal end of said heartwire being free of said distal end of said chest tube for being extendable to a portion of the patient's chest cavity remote from the chest tube.

AMENDED SHEET